Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Special Nutritionals

ARMS#

13408

4 - ER URGENT

000001

[redacted]

Attachment # 1
Memo FLA-9339
CFSAN Project #13408
4/5/99
SJH

Patient ID: [redacted]
Patient Name: [redacted] Age: 39 Sex: M
Registration Date: 02/20/99 2310
Chief Complaint: SEIZURES
Medical Record Number: [redacted]
Time Seen by clinician: on arrival.

Patient arrived via ambulance. Care received during transport included: one amp D50 for glucose in the 40's
The patient's condition upon arrival was stable.
Paramedic states the patient has suspected seizure activity approximately 1/2 hour prior to arrival and lasting minutes. The patient intially appeared to be posticta and has shown improved mental status in the E.D.
There has not been a fever. The patient was not incontinent of urine or stool during the seizure.
There is no history of seizures. Patient without any known history of trauma. The patient does not remember the incident, no preceding palpitations, headache, change in vision
he states he was at work, began to feel a "little week" and the next thing he knew he was on the ground
no witnessed seizure activity
EMS thought that the pt appeared "possibly post ictal"
no history of trauma
per the patient he had very little sleep last pm 4 hours (after a late night)
no food intake today, had several sodas at work and had been taking a natural energy booster

PMH: No other significant current medical problems.
PSH:
Current Medications: none
Allergies: none

SOCIAL HISTORY: The patient lives with family. The patient lives in the local area. The patient is a non-smoker. The patient has no history of alcohol abuse.

REVIEW OF SYSTEMS:
General: No fever, chills, fatigue, loss of appetite, weight gain or loss.
Head: No headache nor recent head trauma.
Eyes: No discharge, altered vision nor pain.
Throat: No sore throat, dysphagia nor hoarseness.
Neck: No pain, stiffness nor swelling.
Neurological: No headache, recent head trauma, vertigo, syncope, numbness nor focal weakness.
Cardiac: No chest pain, diaphoresis, dyspnea on exertion, orthopnea, edema nor palpitations.
Respiratory: No dyspnea, cough, wheezes nor hoarseness. No vomiting, no diarrhea,
Musculoskeletal: No significant joint pain, swelling nor stiffness.
Skin: No rash nor itching.
All remaining systems were reviewed. Information provided by patient/family indicates no significant system abnormalities, except as noted above.

Patient ID: [redacted]
Patient Name: [redacted]

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PHYSICAL EXAM: Vital Signs: See Nurse's notes.
HEAD: Atraumatic, without temporal or scalp tenderness.
EYES: PERRL, EOMI, no discharge or injection. Funduscopic Exam: No papilledema, hemorrhage, or exudates. MOUTH: Mucous membranes moist without lesions, tongue and gums normal.
NECK: Supple, nontender, no lymphadenopathy.
LUNGS: Clear to auscultation and breath sounds equal, no wheezes, rales, or rhonchi. HEART: Regular rate and rhythm. No gallops, rubs or ectopy.
ABDOMEN: Soft, nontender. No masses or hepatosplenomegaly.
NEUROLOGICAL: Alert and oriented. Cranial and cerebellar functions normal. Sensory and motor functions intact.

@ 2320: the patient had generalized seizure activity
treated with ativan

@0030 he is alert and talking with family
labs are pending
no arrythmia
DIFFERENTIAL DIAGNOSIS: hypoglycemia seizure disorder metabolic abnormality

LAB(3): CBC: noted
tox screen: negative

ACCUCHECK: within normal limits.
X-RAY(0):
EKG: narrow QRS, no acute changes. no arrythmia
PULSE OX: Room air 98 INTERPRETATION: within normal limits for this patient
INTERVENTION:
IV: normal saline.
The following medications were given:
Lorazepam 2 IV

CARDIAC MONITOR: A cardiac monitor was attached and the patient's cardiac rhythm was continuously monitored. The tracings showed sinus rhythm as reviewed by the emergency physician.
K+ was low: therfore given 40 meq KCL
he had not eaten all day, he was given a meal, which he ate without problem

discussed with his parents: they believe the energy supplement he is taking contains a significant amount of caffeine

he was observed for > 3 hours s/p seizure activity in the ED
discussed seizure precautions and referral to neurology and 24 hour avail of the ED if any reoccurrence or change
DIAGNOSIS: Seizure, 780.3

DISPOSITION: Patient was discharged home
02:43 accompanied by family The patient's condition upon discharge was stable.
The patient was counseled on the need to follow-up with their personal physician or to return to the Emergency Department if their condition worsens or returns. The patient was advised to follow-up

Patient ID: [redacted]
Patient Name: [redacted]

with [redacted] in 2 days . memo on call

[redacted]
Sun Feb 21, 1999 02:43 am

[redacted]

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E.D. Clinician: [redacted] EMERGENCY DEPARTMENT
Date: Sun Feb 21, 1999 Page 3 of 3 Original

PHYSICAL EXAM Rx PTA- __IV __

Distress- __NAD ✓Alert __convulsing __ ifused (post-ictal)

Pt on init'l arr'l was combative & confused

HEENT
- __nml ENT inspection
- ✓no apparent trauma
- ✓pharynx nml
- __scleral icterus / pale conjunctivae
- __nasal septal hematoma
- __tongue abrasion / laceration
- __hemotympanum
- __TM obscured by cerumen (R/L)
- __tenderness/swelling/echymosis
- pupils 3mm b/l at 0 slgly sl

NECK/BACK
- ✓neck supple
- ✓non-tender
- ✓thyroid nml
- __cerv. lymphadenopathy (R / L)
- __meningismus
- __vertebral tenderness
- __carotid bruit

RESPIRATORY
- ✓no resp. distress
- __breath sounds nml
- __rales
- __rhonchi
- __wheezing

CVS
- __regular rate, rhythm
- ✓heart sounds nml
- __tachycardia / bradycardia
- __irregularly irregular rhythm
- __extrasystoles (occasional / frequent)
- __murmur grade ___ /6 sys / dias
- __decreased pulse(s)

ABDOMEN
- ✓non-tender
- ✓no organomegaly
- __tenderness
- __hepatomegaly / splenomegaly

SKIN
- ✓color nml, no rash
- ✓warm, dry
- __cyanosis / diaphoresis / pallor
- __skin rash

EXTREMITIES
- ✓non-tender
- ✓normal ROM
- ✓no pedal edema
- __pedal edema
- __tenderness

OBSERVED SEIZURE ACTIVITY IN E.D. _____ duration _____
focal / generalized awake / unresponsive
head turned R / L eyes deviated R / L

NEURO/PSYCH
higher functions
- ✓alert
- ✓oriented x3
- __mood/affect nml
- __slow / confused / combative
- __disoriented to *time/place / person*
- __aphasic *expressive / receptive*
- slight cy tt

cranial nerves-
- ✓normal as tested
- __pupils equal, round & reactive to light
- __facial droop (R / L)
- __tongue deviation (to R / L)
- __abnormal accommodation
- __pupils unequal
  R pupil 3 mm L pupil 3 mm
- __EOM palsy
- __abnml fundi *papilledema / hemorrhages*

cerebellar-
- ✓normal as tested
- __abnml Romberg / gait / finger-nose test

sensorimotor-
- ✓no motor deficit
- ✓no sensory deficit
- ✓reflexes nml, symmetrical
- __weakness
- __sensory deficit
- __hyperreflexia / hyporeflexia
- __abnormal reflexes babinski

CBC normal / nml except
WBC ____ bands ____ lymphs ____ eos ____
Hgb ____
Hct ____
Platelets ____

Chemistries normal / nml except
Na ____ BUN ____
K 3.0 Creat ____
Cl ____ Gluc 131
CO2 ____

Drug Levels dilantin ____ phenobarb ____ tegretol ____

Toxicology normal / neg except acetamin. ____

Aspirin ____ ETOH ____
Triage™ urine Negative yesterday
drug screen @ [redacted]

Head CT (nml)

CXR __nml / NAD

EKG __nml __abnormal:

Comparison w/ prior EKG-

Cardiac Monitor __NSR

Pulse Oximeter- time: ____ reading: ____ %

Time ____ __unchanged __improved __re-examined ____

Rigged Fuel: Mahuang Extract 334mg (standardized for 20mg ephedra alkaloids)
Guarana Extract (standardized for 22% Caffeine)
L-Carnitine 100mg
Chromium 200mcg
All per 2 Capsules

2228 Pt c tonic/clonic generalized seizure activity lasting about 1 minute. Pt began unresponsive to verbal answers in the room & then had the seizure.
2235 Dr [redacted] spoke c [redacted] pt

__Hx / Exam limited by [redacted] __Crit Care- ____ min

✓Discussed with Dr [redacted]
will see patient in: office / ED / hospital
__Counseled patient / family regarding:
lab results diagnosis need for follow-up
__Rx given __Admit orders written
__Prior records obtained
__Additional history from:
family caretaker paramedics
__EKG / X-ray examined
__Discussed with radiologist

CLINICAL IMPRESSION: *EMS Arrival*

Seizure
New-Onset Epileptic
Generalized Focal
Grand Mal

Status Epilepticus
Cardiac Dysrhythmia
Cerebrovascular Accident

DISPOSITION- ☐ home ☑ admitted ☐ transferred ____
CONDITION- ☐ unchanged ☐ improved [redacted]

[illegible] signature indicates

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49 **Seizure** (5)

TIME SEEN:_____ ROOM: [redacted]
HISTORIAN: __patient ✓family __paramedic __translator

HPI
chief complaint: (seizure) x1 x2 x3 multiple
hx of seizure disorder

occurred: ✓just prior to arrival _____

witnessed? __no ✓yes, by: family member
~~wife~~ mother

character of seizure(s):
✓lost consciousness
unresponsive
completely partially unknown
did not regain between seizures
_____
__motor activity
generalized "shaking all over"
shaking in one area:
_____
other:_____
_____
_____
__[redacted]continence
__[redacted]ncontinence per EMS
__stopped breathing
__lost pulse
__unknown
_____
_____
_____

number and duration:
__unknown duration / number
__single isolated seizure
duration: _____
__repeated seizures
x2 x3 x4 multiple
__status epilepticus
__continued on arrival in ED

post-ictal symptoms:
__none
✓confusion_____
__lost power/feeling_____
arm / leg R / L
__speech difficulty_____
__visual disturbance_____
__headache_____

injury: head neck nose lip mouth bit tongue
chest abdomen back RUE RLE LUE LLE (none)

preceding symptoms / cause of seizure: ✓none
__missed recent doses of seizure meds_____
__changed medication or dosage_____
__recent alcohol intake_____
__sleep deprivation_____
__recent illness / see ROS_____

__Recently seen/treated by doctor At [redacted] was at work & collapsed. had 4 seizures while @ the ER. wife states pt had low K+

ROS
NEURO
✓headache ~ 4 days
__recent head injury_____

CVS & PULMONARY
__chest pain_____
__palpitations_____
__cough_____
sputum_____
__trouble breathing_____

CONST
__fever_____
EYES & ENT
__trouble with vision_____
__sore throat_____

GI & GU
__abdominal pain_____
__nausea (vomiting) last night
__diarrhea_____
__black/bloody stools_____
__painful / frequent urination

SKIN & LYMPH & MS
__skin rash / swelling_____
__joint pain_____

☐all systems neg. except as marked

Ripped fuel up to 2/day on & off for 1 year

PAST HISTORY ✓negative __see NAS.
__stroke_____ __heart disease_____
__brain tumor_____ __high blood pressure_____
__craniotomy_____ __diabetes *insulin / oral / diet*
__cancer: __known mets_____ _____
_____ __other problems_____
__previous seizure / seizure disorder _____
recent onset / long-standing / since childhood
occasional / frequent / none for years *last seizure:*_____
2° to: idiopathic / head injury / prior stroke / ethanol abuse / cancer
craniotomy / cysticercosis / unsure _____
Records fm [redacted] reviewed

Medications __none __see NAS
__phenytoin_____
__phenobarbital_____
__carbamazepine_____
__valproic acid_____
Ripped fuel by [redacted]

Allergies
✓NKDA __see NAS

SOCIAL HX smoker_____ drugs_____
alcohol (recent / heavy / occasional) rarely
FAMILY HX

000006

[redacted]

M 26

[redacted] *Circle positives, check normals, backslash (\) negatives.*
[redacted]

RUN DATE: 02/21/99 [redacted] LIVE*** PAGE 1
RUN TIME: 0120 ** STAT BROADCAST REPORT **

PATIENT: [redacted] ACCT #: [redacted] LOC: [redacted]
STATUS: [redacted] ROOM:
REG DR: Staff ER Doctor AGE/SEX: 26/M-
ADMIT DATE: 02/20/99 DISCHARGED:

Specimen: [redacted] Collected: 02/20/99-0025 Status: [redacted] Req#: [redacted]
Received: 02/21/99-0027 Subm Dr: [redacted]

Ordered: UR DRG SCR, BL DRUG SCR
Comments: Test to be performed at? [redacted]
HOLD ORDER IN SYSTEM FOR SPECIMEN COLLECTION: N
COLLECTED BY NURSE? N

Test	Low	Normal	High	Flag	Reference	Site
**********CHEMISTRY**********						
THERAPEUTIC DRUG MONITORING						
> ACETAMINOPHEN	2.5			L	10-20 ug/mL	
> SALICYLATE	< 5			L	150-300 mg/L	[redacted]
****SALICYLATE INTERPRETATION****						
**** >300 TOXIC RANGE ****						
TOXICOLOGY						
UR DRG SCR						
BL DRUG SCR						
UR COCAINE		NEGATIVE			NEGATIVE ng/ml	[redacted]
UR THC		NEGATIVE			NEGATIVE ng/mL	
UR AMPHETAMINE		NEGATIVE			NEGATIVE ng/mL	
UR BARBITURATES		NEGATIVE			NEGATIVE ng/mL	
UR BENZODIAZEPI		NEGATIVE			NEGATIVE ng/mL	
UR OPIATES		NEGATIVE			NEGATIVE ng/mL	
UR PCP		NEGATIVE			NEGATIVE ng/mL	
TEST THRESHOLD LEVELS:						
COCAINE: 300 ng/mL						
THC: 50 ng/mL						
AMPHETAMINE: 1000 ng/mL						
BARBITURATES: 200 ng/ml						
BENZODIAZEPINES: 100 ng/ml						
OPIATES: 300 ng/ml						
PCP: 25 ng/nl						
PROPOXYPHENE: 300 ng/ml						
METHADONE: 300 ng/ml						
> S TAD		< 20.0			0-20 ng/mL	[redacted]

[redacted]

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NAME: [redacted] UNIT#: [redacted]

000007

RUN DATE: 02/20/99
RUN TIME: 2334

[redacted]*

** STAT BROADCAST REPORT **

PAGE 1

PATIENT: [redacted]

ACCT #: [redacted]
STATUS: [redacted]

LOC: [redacted]
ROOM:
AGE/SEX: 39/M

REQ DR: Staff ER Doctor

ADMIT DATE: 02/20/99
DISCHARGED:

Specimen: [redacted]
Collected: 02/20/99-2230 Status: [redacted] Req#: [redacted]
Received: 02/20/99-2322 Subm Dr: [redacted]

Ordered: CBC W/DIFF
Comments: Test to be performed at? [redacted]
HOLD ORDER IN SYSTEM FOR SPECIMEN COLLECTION: N
COLLECTED BY NURSE? N

	Test	Low	Normal	High	Flag	Reference	Site
	********** HEMATOLOGY ********** COMPLETE BLOOD COUNT						
	CBC W/DIFF						
>	WBC		9.1			4.8-10.8 K/mm3	
>	RBC		4.97			4.70-6.00 M/mm3	
>	HGB		15.1			13.5-18.0 G/DL	
>	HCT		43.3			40.0-53.0 %	
>	MCV		87.0			80.0-96.0 fL	
>	MCH		30.4			27-31 PG	
>	MCHC		34.9			32-36 %	
>	RDW		13.3			11.5-14.5 %	
>	PLT		251			130-400 K/mm3	
>	MPV		7.6			6.0-9.5 fl	
>	NEUT %	35.9			*L*	46.0-80.0 %	
>	LYMPH %			56.5	*H*	20.5-45.5 %	
>	MONO %		5.2			1.7-9.3 %	
>	EOS %		1.3			0.0-5.0 %	
>	BASO %		1.0			0-2 %	
>	NEUT #		3.3			1.80-7.80 K/mm3	
>	LYMPH #			5.2	*H*	1.10-4.80 K/mm3	
>	MONO #		0.473			0.0-1.00 K/mm3	
>	BASO #		0.1			0-0.3 K/mm3	

[redacted]

Attachment # 1
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4/5/99
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NAME: [redacted]

UNIT#: [redacted]

RUN DATE: 02/20/99
RUN TIME: 2359

[redacted] *

** STAT BROADCAST REPORT **

PATIENT: [redacted]

REQ DR: Staff ER Doctor

ACCT #: [redacted]
STATUS: [redacted]
ADMIT DATE: 02/20/99

LOC: [redacted]
ROOM:
AGE/SEX: 39/M
DISCHARGED:

Specimen: [redacted] Collected: 02/20/99-2230 Status: [redacted] Req#: [redacted]
Received: 02/20/99-2322 Subm Dr: [redacted]

Ordered: CMP
Comments: Test to be performed at? [redacted]
HOLD ORDER IN SYSTEM FOR SPECIMEN COLLECTION: N
COLLECTED BY NURSE? N

Test	Low	Normal	High	Flag	Reference	Site
********** CHEMISTRY **********						
ROUTINE CHEMISTRY						
CMP						
> NA		143			140-148 mmol/L	
> K	3.2			L	3.6-5.0 mmol/L	
> CL		103			101-112 mmol/L	
> CO2	15.8			L	21-32 mmol/L	
> ANION GAP			27.4	H	6-16	
> GLUCOSE			116	H	70-110 mg/dL	
> BUN		15			7-18 mg/dL	
> CREATININE		1.2			0.8-1.3 mg/dL	
> BUN/CREAT		13			6-20	
> TOTAL PROTEIN		7.7			6.4-8.2 gm/dL	
> ALBUMIN		4.6			3.4-5.0 gm/dL	
> GLOBULIN		3.1			2.3-3.5 GM/DL	
> A/G RATIO		1.5			1.1-1.8	
> CALCIUM		9.9			8.8-10.5 mg/dL	
> BILI TOTAL		0.3			0-1.0 mg/dL	
> SGOT/AST		29			15-37 U/L	
> ALK PHOS TOTAL		68			50-136 U/L	

[redacted]

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NAME: [redacted]

UNIT#: [redacted]

[redacted] ID: 20-Feb-1999 22:33:26 [redacted]

26years
Male Caucasian

Room: [redacted]
Loc: [redacted]

Technician: [redacted]

Vent. rate	104 bpm
PR interval	180 ms
QRS duration	82 ms
QT/QTc	302/397 ms
P-R-T axes	50 26 25

Sinus tachycardia
Otherwise normal ECG

000010

Attachment # 1
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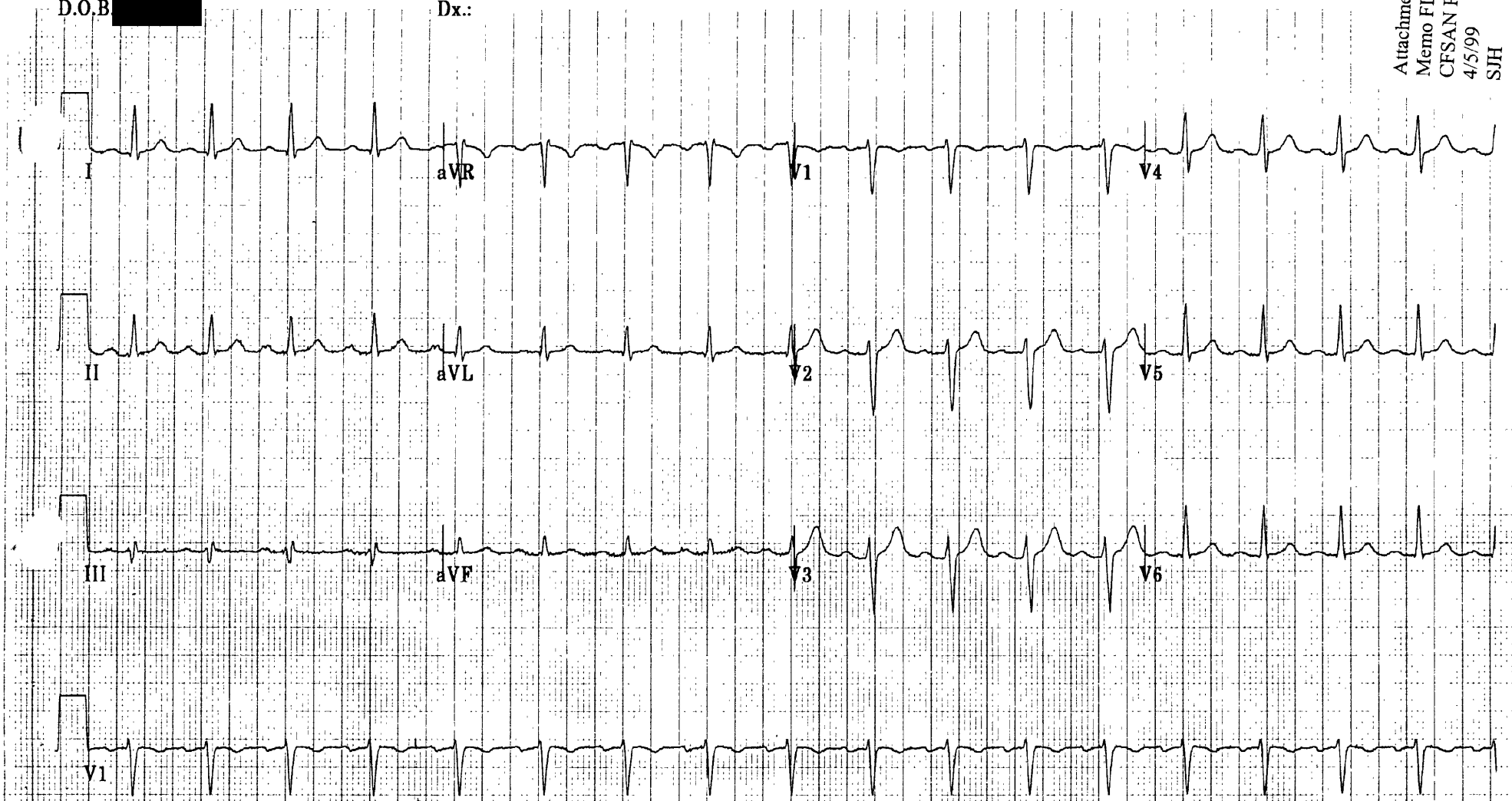
D.O.B: [redacted]

Referred by:

Dx.:

Unconfirmed



100 Hz 25.0 mm/s 10.0 mm/mV 4 by 2.5s + 1 rhythm ld MAC 8 001G 12SL^{tm} v250

[redacted]

Patient	Unit #	Service/Location	Status	Date	Account #
[redacted]	[redacted]	EMERGENCY DEPARTMENT	REG ER	02/20/99	[redacted]

PATIENT

Soc Sec No [redacted] DOB [redacted] Age 26 Sex M MS M Race CA Religion

County: [redacted]

PATIENT EMPLOYER

[redacted]

Occupation:

GUARANTOR

[redacted]

County: [redacted]

Relationship to Patient: PATIENT

GUARANTOR EMPLOYER

[redacted]

Occupation:

OTHER GUARANTOR

SS#:

Address:

Home Ph:

County:

Relationship to Patient:

OTHER GUARANTOR EMPLOYER

Work Phone:

Occupation:

PERSON TO NOTIFY

[redacted]

Work Phone:

Relationship to Patient: WIFE

NEXT OF KIN

[redacted]

Work Phone:

Relationship to Patient: WIFE

INSURANCE #1

[redacted]

Contact

Policy # [redacted]
Coverage #
Subscribe [redacted]
Rel to Pt PATIENT
Eff. [redacted] to Rel Assign Y
Group [redacted]

AUTHORIZATION

Treat/Precert Not Required
Ins Verif [redacted]
Pro Review Not Required
Ins. Name - [redacted]
Ins. Mnemonic - [redacted]

INSURANCE #2

Phone
Contact

Policy #
Coverage #
Subscriber
Rel to Pt
Eff. to Rel Assign
Group

AUTHORIZATION

Treat/Precert
Ins Verif
Pro Review
Ins. Name -
Ins. Mnemonic -

INSURANCE #3

Phone
Contact

Policy #
Coverage #
Subscriber
Rel to Pt
Eff. to Rel Assign
Group

AUTHORIZATION

Treat/Precert
Ins Verif
Pro review
Ins. Name -
Ins. Mnemonic -

OCCURRENCES

Code	Type	Date	Time
[redacted]	ONSET OF SYMPTOMS/ILLNESS	02/21/99	

CONDITIONS

Code Type

Special Program

Attachment # 1
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Last Hospitalization

Admission Comment

Financial Class [redacted]

PHYSICIANS

Attending Physician [redacted]
Prim Care Physician
Admitting Physician [redacted]
Family Physician
Emergency Room Physician [redacted]
Staff ER Doctor
Other Physician

ADMISSION/REGISTRATION

Date	Time	Source	Rm/Bed	Arrival	Principal Admitting Diagnosis/Reason for Visit	Admitted By
02/20/99	2310	EMERGENCY DEPARTMENT	/	AMB	PASSED OUT. SHAKING. CONFUSED	[redacted]

[redacted]

REGISTRATION FORM

Printed 02/21/99 0021